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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,047

Applicant(s)

ITOH ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,9,12,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,9,12,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-5, 8, 10-11, 13-15 have been canceled.
Claims 6-7 have been amended.
Claims 16-17 have been added.
Claims 6-7, 9 and 12, and 16-17 are under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains some NEW GROUNDS of rejections.

Rejections Withdrawn

4. The rejection of claims 7 and 12 under 35 U.S.C. 102(b) as being anticipated by Nakao et al (Cancer Res. 55:4248-4252, 10/1/95, IDS #2) is withdrawn in view of the amendments to the claims.
5. The rejection of claims 6-7 and 12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

Response to Arguments

6. The rejection of newly submitted claims 16-17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained and made again

The response filed 11/4/02 has been carefully considered but is deemed not to be persuasive. The response states that applicants acknowledge that claim 16 encompasses a genus of proteins, however, the examiner seems to take the position that a genus of proteins falling within the scope of claim 16 is not described. The response then directs the examiner to example 9 of the Written Description Training Materials. The response states that the example analyzes written description for a claim reciting isolated nucleic acids that hybridize under highly stringent conditions to the complement of SEQ ID NO:1 and it is noted that only one species falling within the scope of the claimed genus is disclosed and Example 9 clearly states that a person skilled in the art would not expect substantial variation among species encompassed by hybridization conditions. The response further states that the claim of Example 9 and the instant claim 16 are equivalent because both recite highly stringent conditions and a function for the claimed protein. The response further states that the inventors have a second species and the second species would have the same properties as the first species and claim 16 describes the claimed peptides structurally and the claim is limited by hybridization, it must comprise a specific sequence at certain positions and it must have a function.

In response to these arguments, Example 9 of the written description guidelines describes a claim with highly stringent hybridization language and the protein that is

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encoded by such nucleic acid binds to a dopamine receptor and stimulates adenylate cyclase activity. While both claim 9 in the Example and claim 16 in the instant application do describe the hybridization conditions which are highly stringent, claim 16 does not recite a function that is specific to the claimed protein. The claim in Example 9 recites a specific function of binding and activity. While the claim in the instant application, claim 16, does describe some structural aspects of the protein, i.e. comprising the amino acid sequence at positions 749-757, 736-744, 785-793, or 690-698 in SEQ ID NO:2, the claim encompasses any protein with any one of these sequences without functional language. The functional language recited in the claim is not specific for the claimed protein. As evidenced by Boon et al (J.Exp. Med 183:725-729, 1996, IDS #5) there are many tumor antigens that are recognized by T lymphocytes and as evidenced by Rammensee et al (immunogenetics 41:178-228, 1995, IDS #2) there are numerous peptide motifs that bind MHC class I antigen. Thus, the recited function is not special to the claimed peptides.

The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

The following are some NEW GROUNDS of rejections

Claim Rejections - 35 USC § 101

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7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 6-7, 9, 12, 16-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial asserted utility or a well established utility.

The claims are drawn to polypeptides which are disclosed as being tumor antigen peptides and proteins and compositions containing said polypeptide. The specification contemplates a role for these compounds in the treatment/diagnostic of cancer, autoimmune disorders (see page 1). While the specification does disclose SEQ ID No. 2 which is encoded by SEQ ID NO:1, there is no objective evidence, either in the specification or in the prior art of record, which discloses or suggests that SEQ ID No. 2 plays a role in of cancer, autoimmune disorders, or is a tumor antigen. The specification teaches that peptides derived from SEQ ID NO:2 bind to HMC I antigens and are recognized by CTLs. The specification also discloses that the mRNA for the tumor antigen protein gene was present in various cancer cell lines and normal tissues (see Figure 1 and page 32). Thus there is no differential expression of the claimed protein or peptides in any tissue.

As evidenced from Kast et al (Journal of Immunology 152:3904, 1994, IDS#2) HLA motifs and binding to CTL is found in human papillomavirus type 16 E6 and E7 proteins and these are clearly not tumor antigens. Thus just because there is a

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correlation of the claimed peptides and this observation does not result in the proteins being tumor antigens.

There is no correlation between this suggested use and cancer, autoimmune disorders and/or Alzheimer's disease. Thus, there is no objective evidence of record to show that SEQ ID No. 2 plays a specific role in cancer, autoimmune disorders. Thus, these asserted utilities are not considered "specific" utilities, ie. they are not specific to the claimed compounds' properties. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed polypeptides/antibodies. Therefore, for the reasons stated above, the claimed invention of polypeptides and compositions containing said polypeptides is not supported by a specific utility.

9. Claims 6-7, 9, 12, 16-17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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11. Claims 6-7, 9, 12, 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to a tumor antigen and peptides of such that the peptides bind HMC I antigen and are recognized by CTLs. The specification discloses SEQ ID NO:2 and peptides from SEQ ID NO:2. The specification discloses that mRNA of the gene for the tumor antigen is expressed in various cancer lines and in normal tissues (see Figure 1). The specification speculates that the protein and peptides are tumor antigens.

As evidenced from Boon et al (J. Exp. Med 183:725-29, 1996,IDS 5) there are many ubiquitous antigens that are recognized by CTLs and unless the gene shows a much higher degree of expression in tumor cells one would not know how these antigens could be used (see page 726). In addition, Kast et al (Journal of Immunology 152:3904, 1994, IDS#2) teach HLA motifs and binding to CTL is found in human

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papillomavirus type 16 E6 and E7 proteins and these are clearly not tumor antigens.

Thus just because there is a correlation of the claimed peptides and this observation does not result in the proteins being tumor antigens.

Therefore, in view of the lack of guidance in the specification and in view of the unpredictability in the art as evidenced from Boon et al and Kast et al and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

Summary

12. No claims are allowed

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to read 'L. Helms', with a stylized flourish at the end.